

endoluxe

WIRELESS VISUALIZATION SYSTEM



eVS User Manual (Instructions for Use)

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1. Introduction

1.1. Intended Use

The Endoluxe Vision System (eVS) is a wireless battery operated digital camera with light source intended for use as an illuminating, imaging and image data acquisition system for a variety of endoscopic procedures, used in conjunction with a fiber optic (analog) endoscope.

This product should only be use by practicing physicians capable of performing the prescribed endoscopic procedure using endoscopic equipment as appropriate for the procedure.

Procedure time should be considered as the camera and light source are both battery operated and have a limited procedure time dependent upon light intensity setting and data capture functions utilized. A wired mode using the optional USB-C cable accessory to power the battery operated camera from the Receiver can be utilized for longer procedures.

1.2. Environments

The eVS is intended to be used in typical indoor clinical and hospital environments per specified operating conditions, under controlled temperature and humidity, and reasonable altitude conditions for healthcare facilities. The system is susceptible to Wi-Fi interference and will perform best if located a reasonable distance from other Wi-Fi and RF enabled equipment.

1.3. Essential Performance

The eVS Orb (wireless camera) will display the image as would be seen directly from the endoscope eye piece. Orb control is by touch screen or from peripheral input to the Receiver connected to an HDMI enabled remote display. The Orb is completely wireless and battery operated.

In extreme conditions the image can be lost on the remote display, or Orb battery charge depleted resulting in loss of view. Should the Orb view be lost, it can quickly be decoupled from the endoscope providing direct access to the endoscope eye piece for safe removal of the endoscope.

1.4. Stacking

The eVS Charger and Receiver are designed to be stacked should this configuration be optimal. The Charger can be located anywhere around other equipment and devices, and away from treatment areas. The receiver can be placed anywhere within proximity to an HDMI enabled remote display, and with other equipment and devices. To ensure uninterrupted Orb and Receiver connection, Receiver should be located a reasonable distance from other Wi-Fi routers and repeaters.

1.5. Certifications

Wi-Fi and Bluetooth Modules are FCC Certified for Equipment Classes: Digital Transmission System, Part 15 Spread Spectrum Transmitter, and Unlicensed National Information Infrastructure TX. FCC ID: Z64-WL18DBMOD

Electrical safety testing and certification performed by MET Labs.

Orb	IEC 60601-1:2005 + A1:2012 IEC 60601-1-6:2010 + A1:2013 IEC 60601-2-18:2009
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Receiver and Charger	UL 62368-1, Second Edition CSA C22.2 No. 62368-1 Second Edition
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1.6. Trademarks

The Adopted Trademarks HDMI, HDMI High-Definition Multimedia Interface, and the HDMI Logo are trademarks or registered trademarks of HDMI Licensing Administrator, Inc. in the United States and other countries.

1.7. Manufacturing

Manufactured for Endoluxe by AVG, 4140 Utica Ridge Rd, Bettendorf, IA 52722.

2. Warnings

- 2.1. Read the complete eVS User Manual for all warnings and detailed operating instructions.
- 2.2. Do not modify system devices or accessories.
- 2.3. There are no user serviceable components. Do not attempt to disassemble, modify, or service any of product devices or accessories.
- 2.4. Take all precautions to keep from dropping the Orb.
- 2.5. Do not submerge Orb, Charger, Receiver, Power Supply, or accessory cables.
- 2.6. It is recommended to only power the light source when the Puck is magnetically coupled to the Light Adapter mounted on an endoscope. The Puck LED when used at higher intensities will get hot. Do not look directly at the Puck LED when it is illuminated.
- 2.7. Highly recommended that Receiver power be provided by UPS to avoid issues by power interruptions during procedures.
- 2.8. Do not place other Wi-Fi or RF equipment between the Receiver and the area(s) where the Orb will be used for procedures. Portable RF communications equipment including antennas can effect eVS device Wi-Fi connections and performance. The Receiver should be placed at least 1M away from other RF transmitters, Wi-Fi routers or repeaters.

NOTE: *The emissions characteristics of the eVS make it suitable for use in industrial areas and hospitals (CISPR 11 class A.) If used in a residential environment (CISPR 11 class B normally required) the eVS might not offer adequate protection to radio-frequency communication services. Mitigation measures such as relocating or re-orienting the Receiver might be necessary.*

- 2.9. Endoluxe specified and supplied power supplies, cables and accessories must be used to maintain electrical safety compliance.
- 2.10. Do not connect the Orb to any USB interfaces or cables other than the Charger, or the Receiver using the USB-C cable optional accessory.
- 2.11. The Orb will shut down when the battery charge is depleted and Puck LED illumination will be lost. Highly recommended that a secondary or backup illumination source is accessible when performing procedures. Also recommended to use wired mode optional USB-C cable accessory for longer procedures where battery charge time is an issue.

3. System Components and Accessories

3.1. Orb (Camera Head and Light Source), Charger, and Receiver

Orb (1114)

Camera with touch screen display and integrated LED light source with universal endoscope coupler



Charger (1115)

Orb charging and storage



Receiver (1116)

HDMI output for remote display and data storage



3.2. Accessories

Endoluxe supplied power adapters, components, cables and other accessories must be used to maintain electrical safety compliance, and can be ordered using the listed part numbers.

- 1117 - Light Adapter, 13mm
- 1118 - Light Adapter, 14mm
- 1119 - Light Adpater, 43mm
- 1120 - Power Adapter
- 1123 - Mouse.
- 1122 - HDMI Cable.
- 1121 - USB-C to USB-C Data/Power Cable (optional accessory)

4. Setup

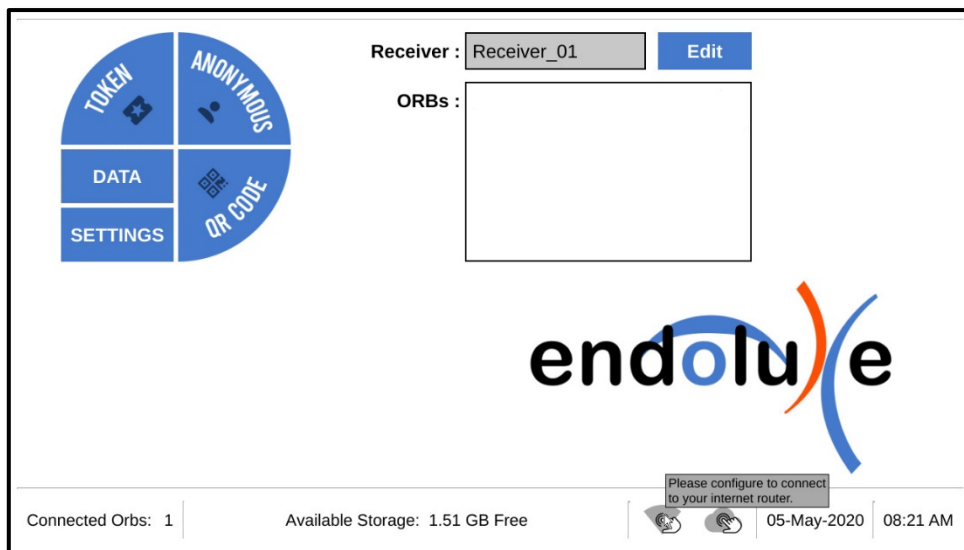
4.1. Connect and Configure your Receiver

Locate the Receiver in close proximity to the remote HDMI enabled display, but at least 3 feet away from other Wi-Fi routers or repeaters.

- Connect your remote display to the Receiver using the supplied HDMI cable.
- Connect the supplied mouse to the Receiver.
- Connect the supplied Power Adapter to the Receiver.
- Power up the Receiver by plugging the Power Adapter in to an electrical outlet. It is highly recommended that an Uninterrupted Power Supply (UPS) is used.

Use of an extension cord or unprotected multiple socket outlet or power strip is not recommended. The Power Adapter plug should be easily accessible as an acceptable method to disconnect the eVS in wired mode from main power.

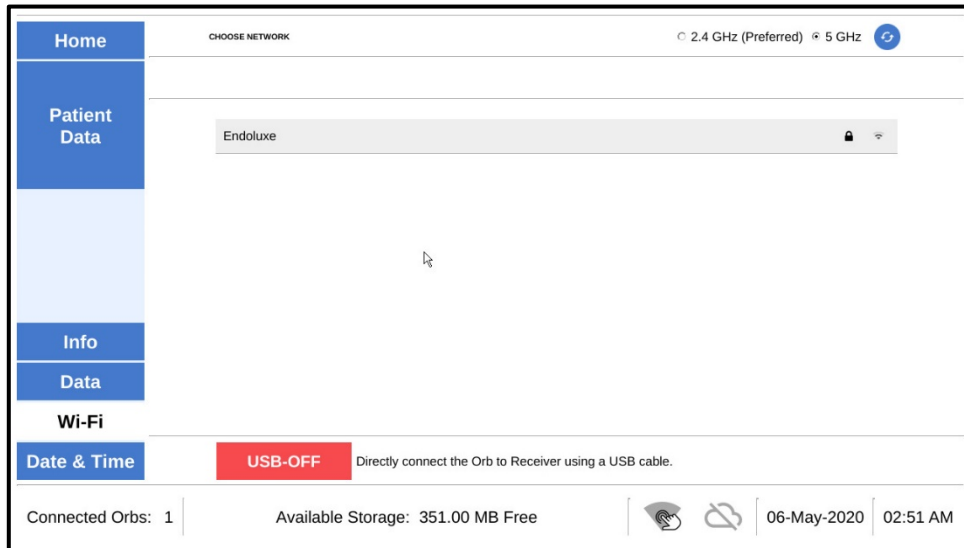
- Wait for the home screen to be displayed.



TIP: You can rename the Receiver by clicking on the Edit button. This is useful if you have multiple Receivers and want to identify them with familiar names.

- Click on the Wi-Fi icon in the footer area or navigate to the router setup screen by clicking on Settings, then clicking on Wi-Fi from the Settings screen.
- Select your router and enter the router password. Note that 2.4 GHz is preferred for a wider coverage area.

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The Wi-Fi icon in the footer will be solid black once the Receiver is connected.



The Receiver should be left powered on and connected to your remote display. It can be turned off from the user interface if it is going to be out of use for an extended period of time.

4.2. Power the Charger

- Connect the supplied Power Adapter to the Charger.
- Power up the Charger by plugging the Power Adapter in to an electrical outlet.

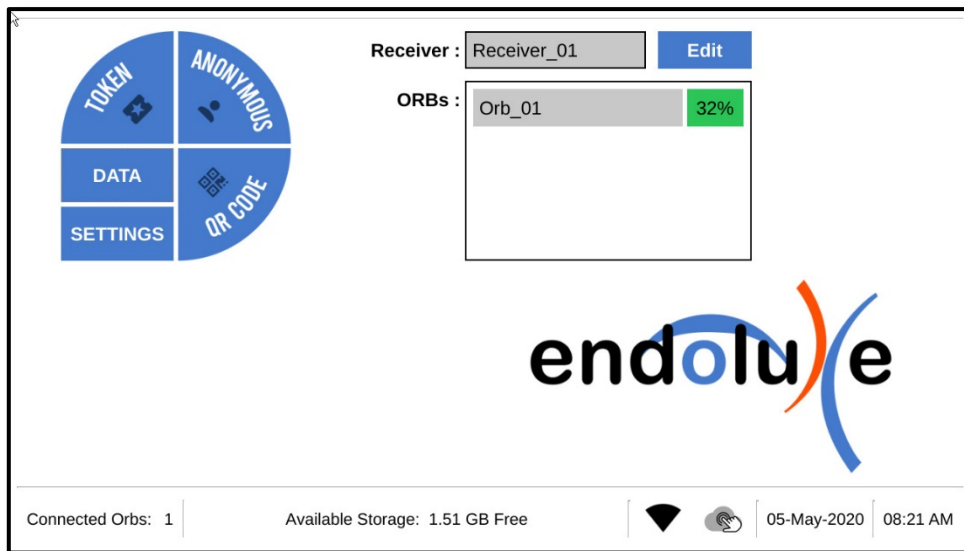
4.3. Charge Your Orb

- Place your Orb in the Charger with the charging port and coupler aligned to the Charger. Firmly push down until the Orb is completely seated in the Charger. Positive docking will turn the Orb on and be indicated by illumination of the Orb light ring.
- Charge for at least 90 minutes prior to initial use or until light ring indicates blinking or solid green.
- Store the Orb docked in the Charger when not in use to ensure it is charged and ready for the next procedure, and to prolong the life of the battery.

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- Verify the Orb has paired with the Receiver. Once powered up the Orb will automatically pair with the closest available Receiver within a few minutes and show up on the home screen list of connected Orbs.

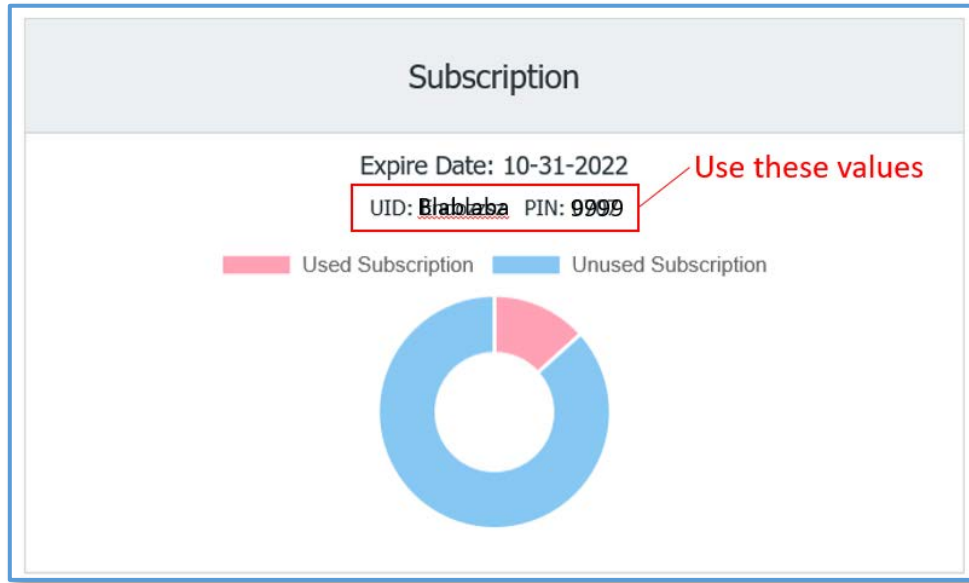


TIP: You can rename the Orb by clicking on the Orb name in the list of connected Orbs. This is useful if you have multiple Orbs and want to identify them by name.

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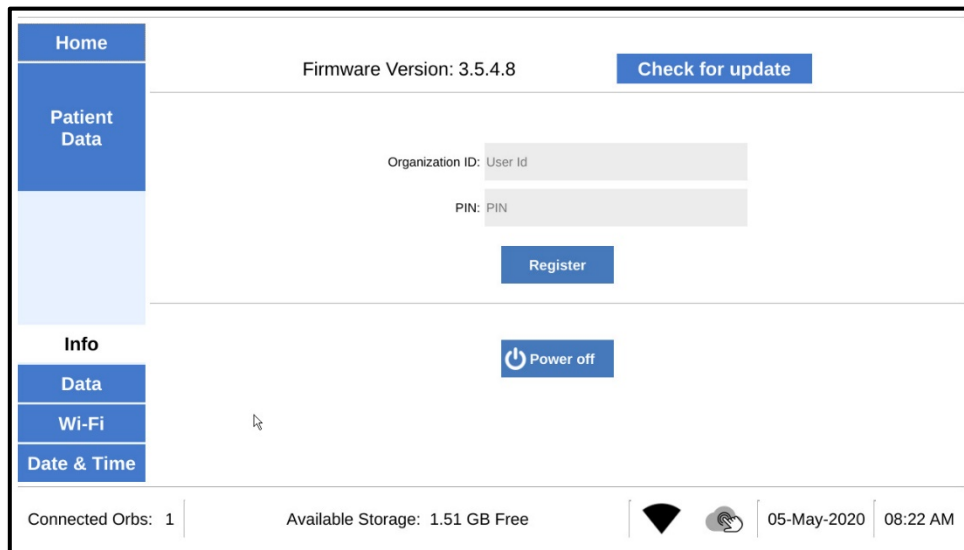
4.4. Register Your eVS at Collective.Endoluxe.com

- Log in to the Collective.Endoluxe.com with the Organizer credentials provided at the time of your initial purchase of the eVS. Contact Support if you need login assistance.
- Write down the UID and PIN for your Collective.Endoluxe.com Organization as listed in the Subscription panel.



UID _____ PIN _____

- Ensure the Receiver is connected to your external router.
- Navigate to the Settings info screen and enter your Organization's UID and PIN, click on Register.



Once successfully registered the cloud icon in the footer will be solid black.



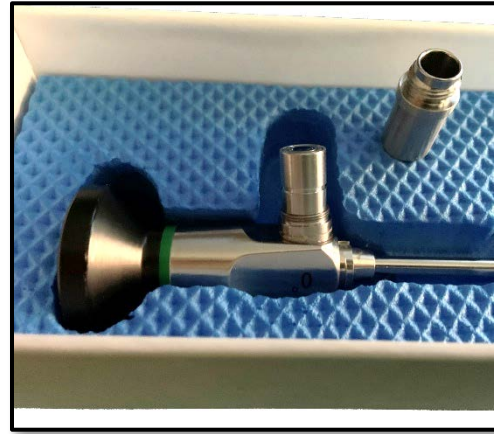
4.5. Install a Light Adapter

It is necessary to install a Light Adapter to the light port of your endoscope to allow the Puck light source to magnetically attach. Standard 13mm Light Adapters are provided with each Orb. Typically the endoscope light port will have a universal thread size that matches with the eVS Light Adapters.

Many endoscopes come with multiple light port adapters or collars. You may need to remove the other adapter(s) or use one of them to accept and screw on the eVS Light Adapter.



Light port with collar.



Light port with collar removed to accept the eVS Light Adapter.

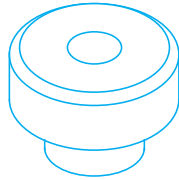
- Screw the eVS Light Adapter on to your endoscope's light port. Ideally the Light Adapter will be flush with the top surface of the light port when screwed all the way down.



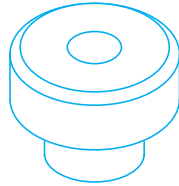
eVS Light Adapter with correct positioning, flush with light port.

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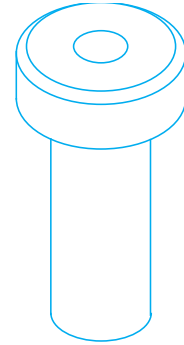
Endoluxe offers Light Adapters in multiple lengths to accommodate various light port and endoscope configurations to ensure proper positioning for best results. Contact customer support if you need assistance determining the best Light Adapter length for your equipment and to acquire additional Light Adapters.



1117
13mm Light Adapter
(Standard)

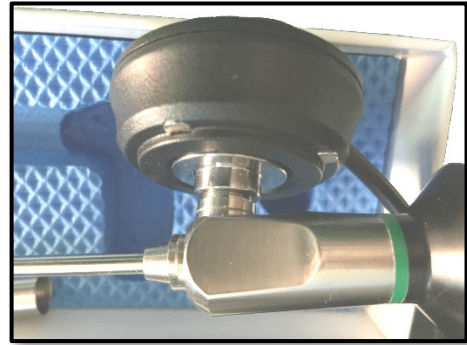


1118
14mm Light Adapter



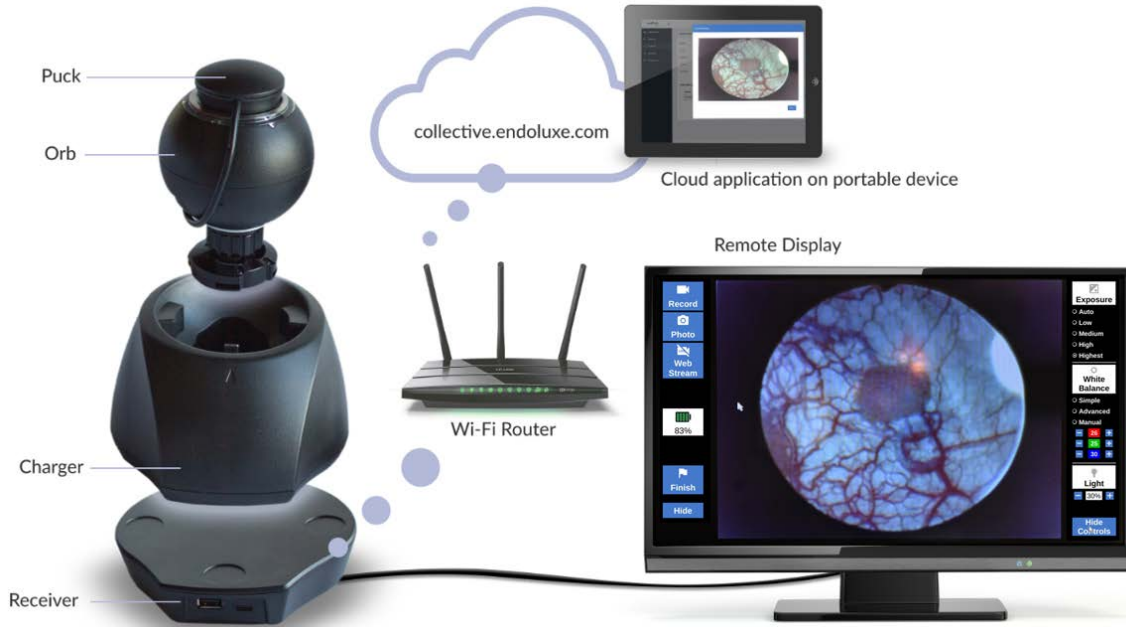
1119
43mm Light Adapter

Correct placement of the Puck magnetically attached to the eVS Light Adapter installed on a rigid endoscope light port.



5. Basic Operation

The Orb is a battery operated digital camera and LED light source that will couple to an analog endoscope. The camera and light functions can be controlled using the Orb's touch screen display or the remote display. The Orb wirelessly connects to the Receiver which enables live streaming and control with a remote display. The Receiver should be connected to an external WI-FI internet router to enable live streaming and uploading of image data files to the collective.endoluxe.com cloud application, and automatic firmware updates.



The eVS is designed to have a single Orb paired with a single Receiver connected to a remote display during a procedure. Many Orbs can be connected to a single Receiver or used in a multiple Receiver environment.

The Orb and Light Adapter should always be cleaned in accordance with patient environment requirements prior to the intended procedure. Cover all parts of the Orb with a sterile drape or cover for ultra clean or sterile procedures. The optional USB-C cable should also be wiped down and if necessary covered for wired mode. The Receiver, Charger, and all other components should be kept outside clean or sterile patient areas.

The eVS has three endoscopy procedure modes for visualization and image data capture.

Anonymous Collected imagery data will not be associated to a specific patient or scheduled case.

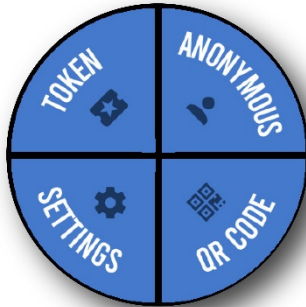
QR Code Collected imagery is associated with a specific patient from a scan of the QR code generated from the patient record on the collective.endoluxe.com. Files are stored using the patient name and code.

Token Data is associated with a specific patient and scheduled case from cases set up using the collective.endoluxe.com. Files are stored using the patient name, code and case date code.

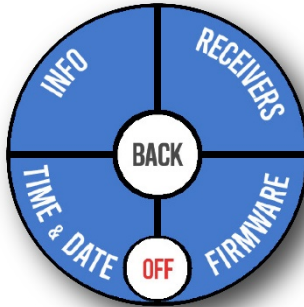
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5.1. Orb Operation

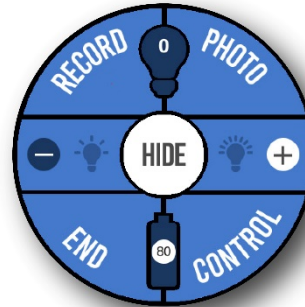
- Dock the Orb in the Charger to power it up if it has been turned off.
Note: Booting may take several minutes as the Orb is checking for firmware updates and attempting a Wi-Fi pairing to an available Receiver.
- Remove the Puck to wake the Orb. Touching the screen will wake the touch screen if the Orb has been asleep for over an hour.
- Touch the Orb screen to navigate through the user interface and control the system.



Home Screen



Settings Screen



Procedure Screen

- Place the Puck back on the Orb to put it to sleep.

Light Ring Status Identification

Color	State	Meaning
Red	Solid	Boot failure
Blue	Solid	Booting, checking or updating firmware
White	Solid (five seconds)	Correctly docked in the Charger
White	Blinking (fast or slow)	Battery charging
White / Green	Blinking	Battery charging, acceptable charge for procedure start
Green	Blinking or Rotating	Acceptable charge for procedure start
Green	Solid	Battery at full charge
Yellow	Blinking	Battery charge low and Orb should be charged
Red	Blinking	Very low battery charge with shut down pending
	Off	Normal operation or sleeping

Warning: Do not look directly at the Puck LED when it is illuminated!

The Orb will show warning messages for certain conditions and to let you know when the charge is low.

The Orb will power down if left undocked with the Puck on for over two hours. If this happens just put the Orb back in the Charger to turn it back on.

5.1.1. Pairing with a Receiver

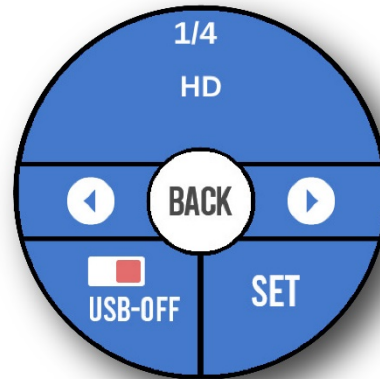
The Orb will always attempt to reconnect with the last configured Receiver or the closest available Receiver. It can be manually paired to a Receiver if you have a multiple Receiver environment, or there was some other issue preventing an automatic connection, or the connection was dropped.

- Navigate to Settings > Receivers on the Orb. The Orb will scan for available Receivers. Tap the BACK button and then return to the Receivers screen to rescan if necessary.
- Use the forward and back arrows to find your desired Receiver.

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- Tap SET and wait for the Orb to connect. A second attempt to pair might be required depending on the proximity of the Receiver(s) and other environmental conditions.

Receiver connection screen



5.1.2. Coupling the Orb to an Endoscope

- Push in the spring clamp of the coupler and place Orb coupler over your endoscope's eyepiece. Release the spring clamp. Ensure the coupler is completely seated over the eyepiece.

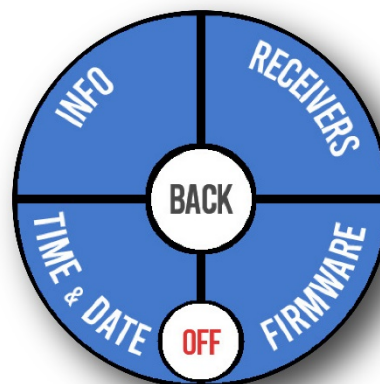


- Attach the Puck to an installed Light Adapter. (See Section 3.5: Install a Light Adapter)

5.1.3. Orb Storage When Not in Use

The Orb should always be docked in the Charger when not in use to optimize battery life. It can be turned off from the Settings screen if it is going to be out of service for an extended period of time, or transported.

Orb off button from the settings screen.

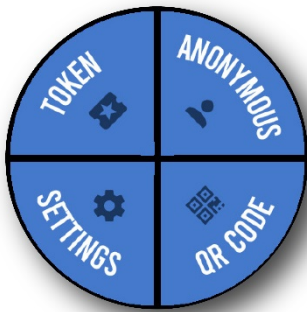


5.2. Using the eVS (Controls)

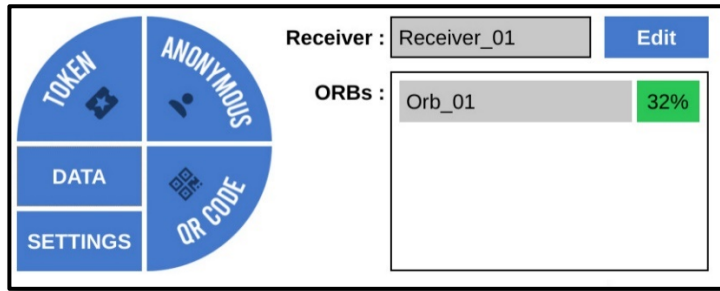
5.2.1. Starting and Stopping a Procedure

Anonymous, **QR Code** and **Token** are the three procedure modes.

- Select a procedure mode from either the Orb or the Receiver home screen to start a procedure.

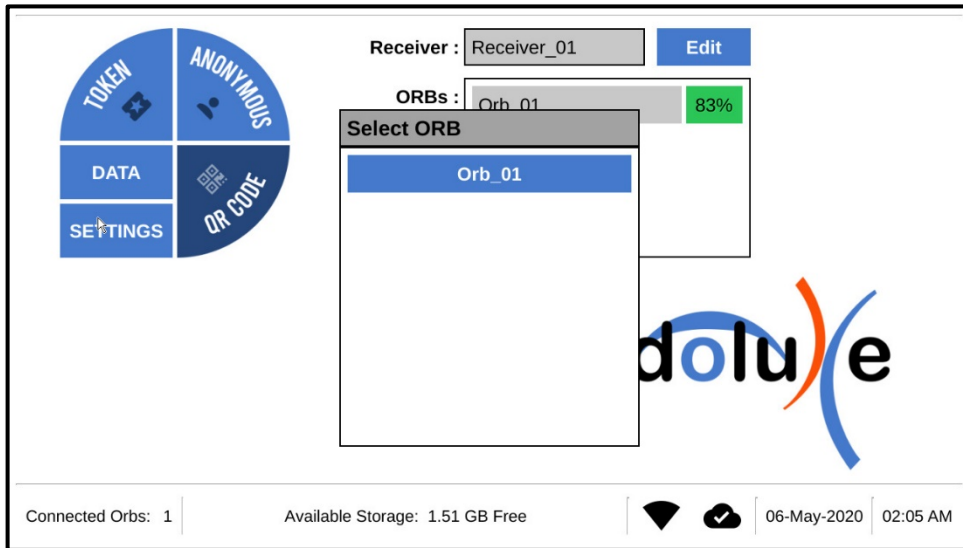


Orb home screen



Receiver home screen

- Select the Orb you are using from the remote display when procedure mode is initiated from the remote display.



Anonymous – Collected imagery data will not be associated to a specific patient or scheduled case.

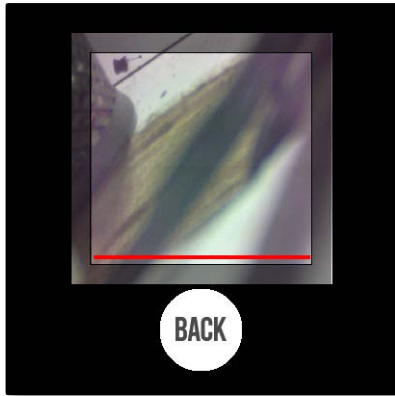
QR Code – Collected imagery data is associated with a specific patient from a scan of the QR code generated from the patient record on the collective.endoluxe.com.

- Print the QR code for your specific patient from the collective.endoluxe.com patient record.
 - Navigate to the Patients screen.
 - Find your patient and click on the printer icon.

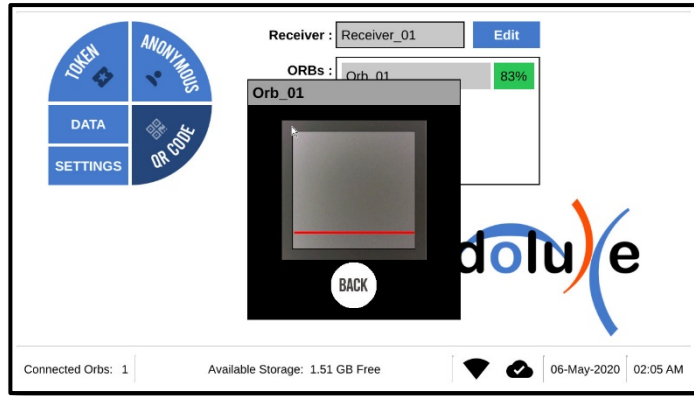


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- Scan the patient QR code using the Orb prior to attaching it to an endoscope by pointing the coupler at the QR code.



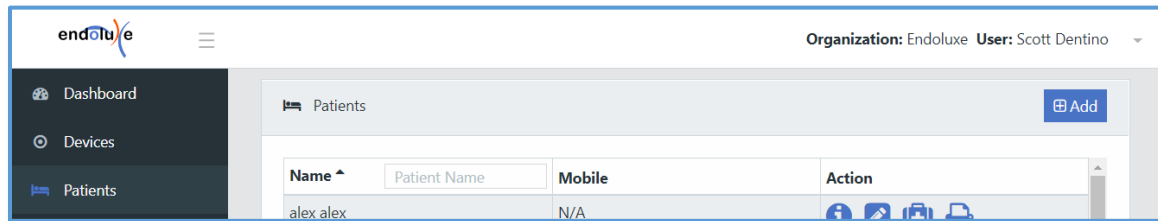
Orb scan QR Code



Receiver scan QR Code

Token – Collected imagery data is associated with a specific patient and scheduled case from cases set up using the collective.endoluxe.com or remote display.

- Create a patient record by clicking on +Add from the Patients screen of the Collective.Endoluxe.com.



- Enter relevant patient information.

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Add Patient

Note: The following * fields are mandatory.

Firstname *

Lastname *

Gender * Male Female Other

Date of Birth *

Email

Mobile

Address

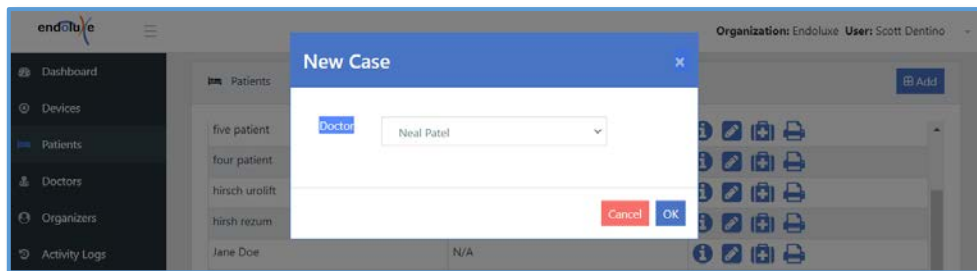
City

State

Country

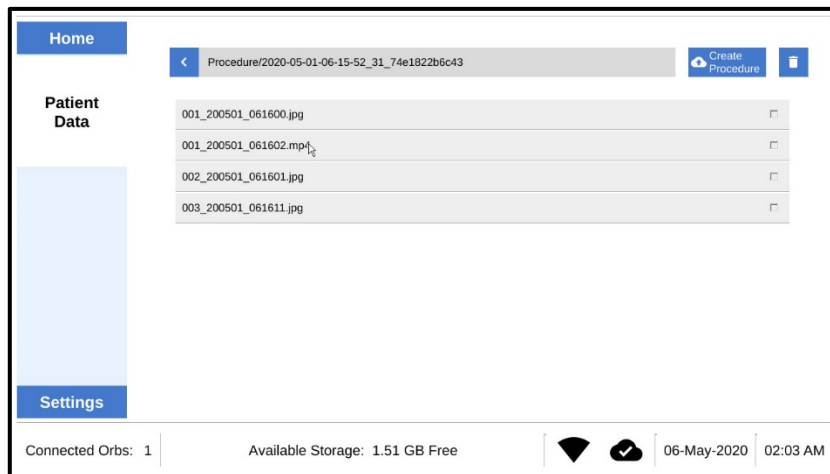
Zipcode

- Find the patient in the list of patients and click on the New Case Icon. Select the physician assigned to the procedure and schedule the case.



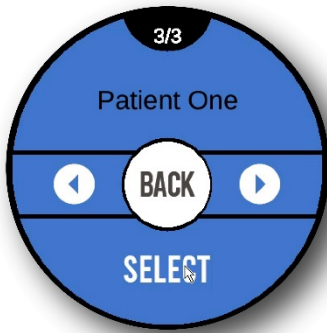
Patients and cases can also be created from the Remote display.

- Select an existing patient from the Patient Data screen and click on Create Procedure.

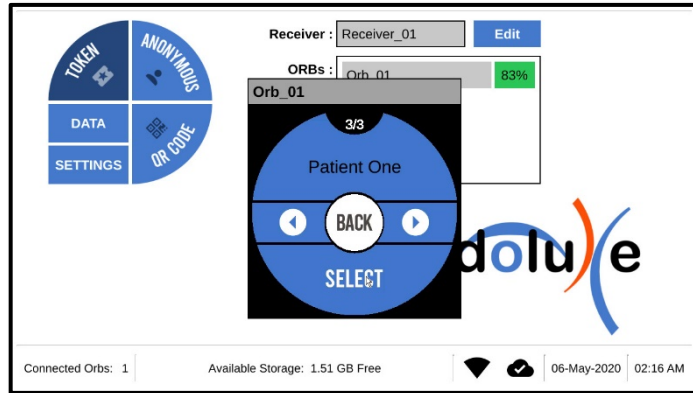


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- Now select the patient from the list; page through the list using the arrows then SELECT when the correct patient name is displayed.



Orb Patient Select

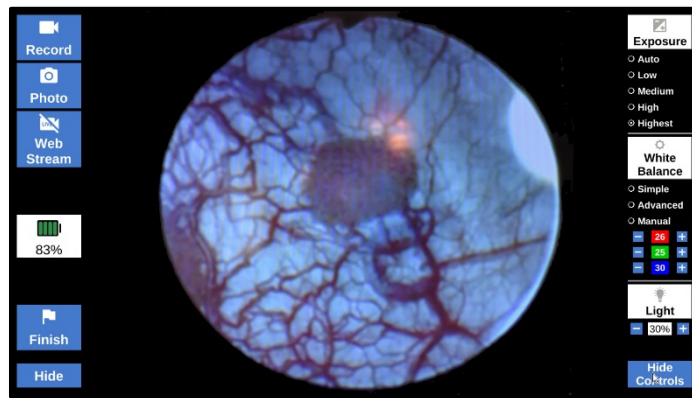


Remote Display Patient Select

- Touch **END** from the Orb procedure screen or click on **Finish** from the remote display procedure screen to exit procedure mode.



Orb Procedure Screen



Remote Display Procedure Screen

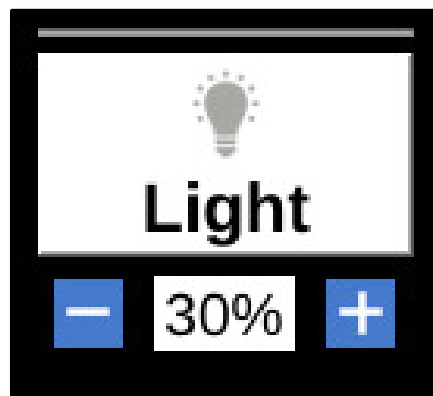
- Wait while any captured video or image files are uploaded to the Receiver.

5.2.2. Adjusting the Light Source Intensity

Puck LED intensity can be set from the Orb procedure screen or remote display procedure screen right panel controls by touching or clicking either "+" or "-".



Orb Puck Light Intensity Controls



Remote Display Light Intensity Controls

5.2.3. Capturing Video and Pictures

TIP: The Orb procedure controls and indicators can be hidden by touching HIDE. Tap the screen to bring them back overlaid on the endoscope view.

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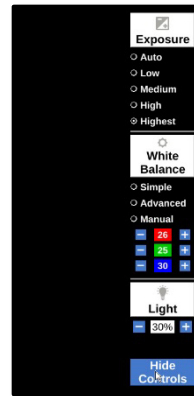
- 5.2.3.1. Recording Video
 - From the Orb touch Record.
 - From the Remote display click on Record.
- 5.2.3.2. Take a picture
 - From the Orb touch Photo
 - From the remote display click on Photo

5.2.4. Adjusting the View (White Balance and Exposure)

White Balance and Exposure settings can be controlled from either the Orb procedure control screen or the remote display right control panel.



Orb Image Controls



Remote Display Image Controls

5.2.4.1. White Balance.

Simple Mode The Recommended setting, providing the best image in most conditions. Uses an average color temperature to balance.

Advanced Mode Uses color temperature to detect white areas and balance.

Manual Mode Enables direct setting of Red, Green, and Blue (RGB) values.

- 5.2.4.2. Both Simple and Advanced modes are automatic, providing real time adjustment.
- 5.2.4.3. Manual mode enables direct setting of Red, Green, and Blue (RGB) values.
 - Set WHITE BALANCE to Manual.



Orb White Balance Control



Remote Display White Balance Control

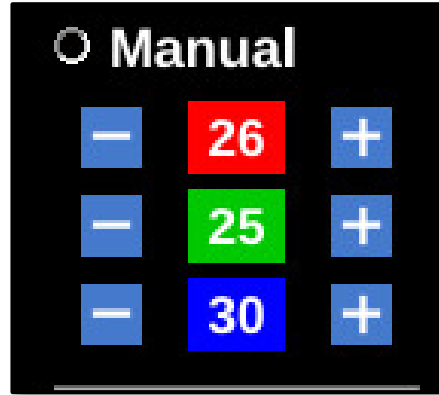
- Select R G or B if adjusting from Orb.

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- Use + and – to adjust the color to your desired balance level.



**Orb Manual White Balance
R G B Settings Controls**



**Remote Display Manual White Balance
R G B Settings Controls**

5.2.4.4. Exposure can be set to Auto, Low, Medium, High, and Highest.



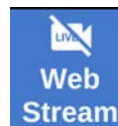
Orb Exposure Control



Remote Display Exposure Control

5.2.5. Live Stream a Procedure

Live streaming utilizing Collective.endoluxe.com can be enabled during a procedure by clicking the Web Stream control in the left panel of the remote display.



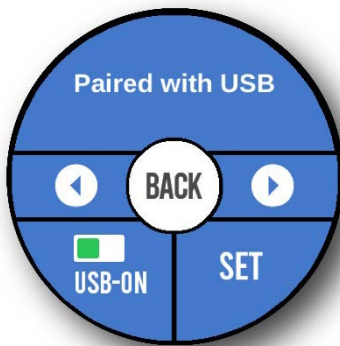
eVS User Manual (Instructions for Use)

5.3. Wired Mode

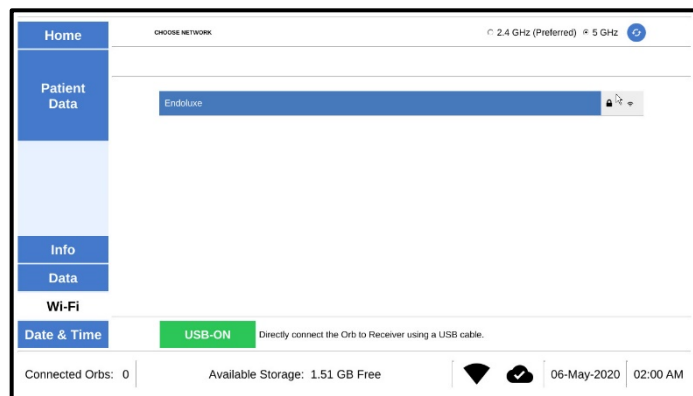
Wired mode can be initiated at any time and is provided for extreme conditions where procedures are extremely long exceeding battery charge time, or the Orb and Receiver are subject to being within close proximity to other powerful Wi-Fi or RF emitting equipment that inhibit a Wi-Fi connection between the Orb and Receiver.

In wired mode the Orb is powered by the Receiver directly connected to the Receiver using the optional accessory 1050 – USB-C to USB-C data and power cable.

- Connect the USB-C cable to the Orb charging port and then to the USB-C port on the front of the Receiver. Both the Orb and Receiver will detect the USB-C cable and automatically enable wired mode.



**Orb Settings – Receivers
USB ON for Wired Mode**



**Receiver Settings – Wi-Fi
USB ON for Wired Mode**

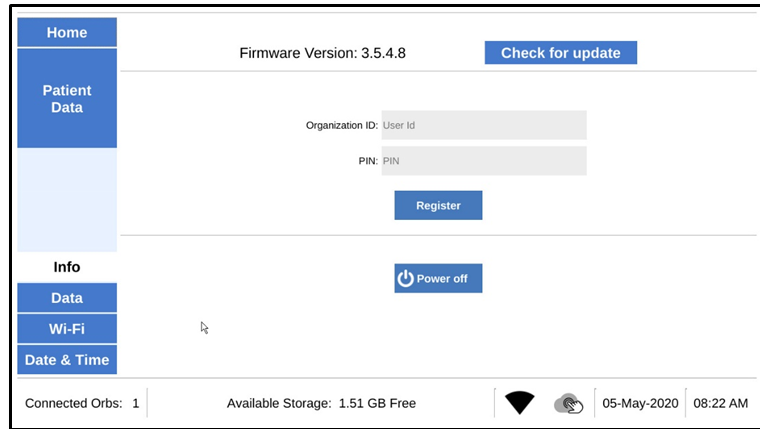
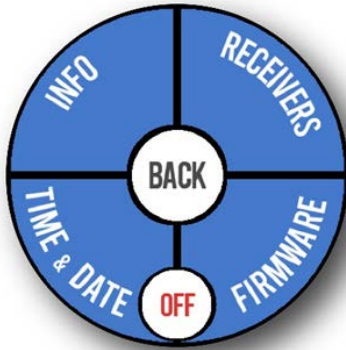
The Orb and Receiver can be also manually be set to Wired mode by enabling the USB-ON from the Orb Settings > Receivers screen and enabling USB-ON from the Receiver Settings > Wi-Fi screen.

- Disconnect the USB-C cable from both the Orb and Receiver to reset to normal Wi-Fi mode.

5.4. Firmware Updates

Firmware updates are periodically released to implement improvements and enhancements. Under normal operating conditions both the Orb and Receiver will automatically update with the latest firmware version. The Receiver will check and update if necessary upon powering up as well as each night. The Orb will also check and update if necessary when booting, and each night if docked in the Charger.

Firmware can be checked and updated if necessary using the Orb settings screen or the Receiver Settings > Info screen.

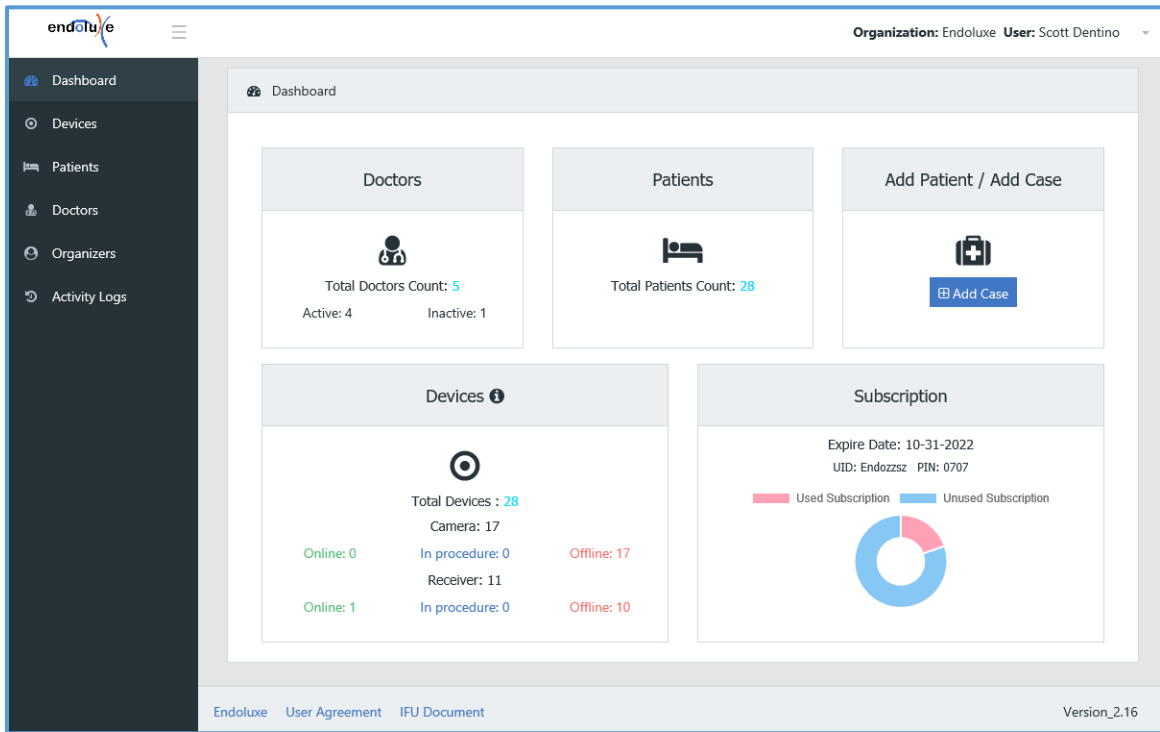


Orb Settings Screen

- Touch on Firmware to check and update the Orb firmware. Touch update if there is a later version to install. It will take a few minutes to update, configure and then reboot.
- Click on Check for Update to update the Receiver firmware. Click on update if there is a later version to install. It will take a few minutes to update, configure and then reboot.
- Leave the Orb docked in the Charger or powered on until the update completes.
- Leave the Receiver powered up until the update completes.

Remote Display Settings – Info screen

5.5. Using the Collective.Endoluxe.com (Integrated Cloud Application)

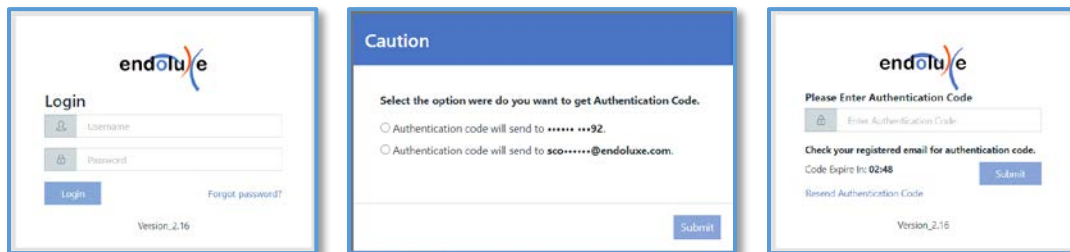


5.5.1. Introduction and Roles

The Collective (<https://Collective.Endoluxe.com>) is a cloud application available to eVS owners with an active annual subscription. It is fully integrated with the eVS and is designed for maximum productivity, cloud storage of patient files, and to host live streaming of procedures. The application can be accessed by virtually any device with browser capability and internet access.

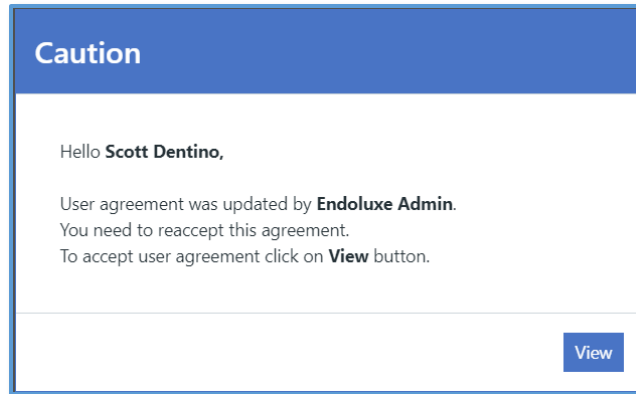
The Collective home page with dashboard as shown above contains key information at a glance, with each of the areas linked to the specific detail screens. The right header area shows your Organization and user information with a dropdown to enable user profile management. The footer provides links to important information such as the User Agreement, this user manual, and the Endoluxe public website.

Login requires two stage authentication with a username (typically your email address) and password, and a security code provided either by text or email based upon the email address or phone number entered in your user profile. From time to time you will be required to provide a security code at login or when you access the application from an unrecognized device.

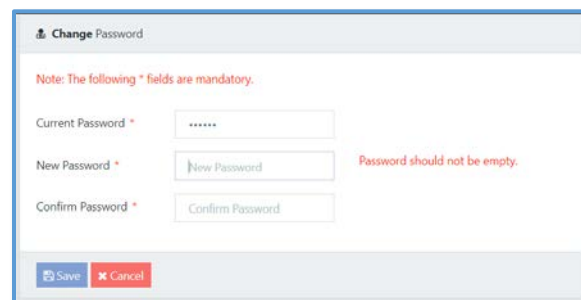
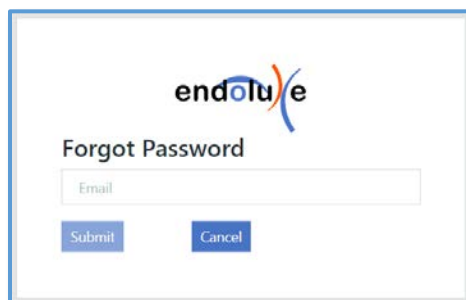


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You must accept the User Agreement with your first application visit or anytime there is an amendment to the User Agreement. Scroll to the bottom of the agreement to activate the Accept button.



The Forgot password link can be used if you need to reset your password. A new password will be emailed to the address entered. Then you will be prompted to change your password when you log in with your username and temporary password received via email.



There are three basic user roles for the application; *Organization*, *Organizer* and *Doctor*.

eVS User Manual (Instructions for Use)

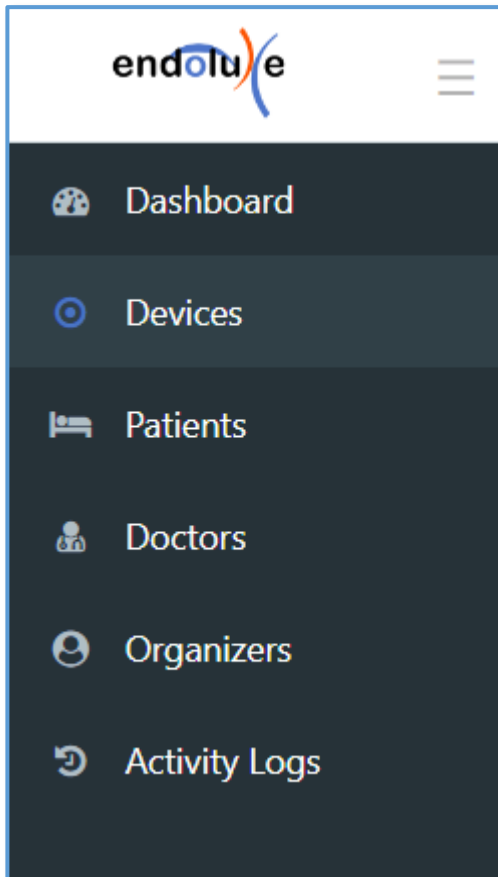
Organization An Organization is created for your institution or practice at the time of initial eVS purchase. Your Organization can include multiple sites or be for a single site or office location.

Organizer A primary Organizer is created as part of the initial Organization set up. The Organizer is the site administrator and can see everything with full functionality, including adding additional Organizers.

Doctor Doctors can create procedures, add and view patient records.

5.5.2. Basic Set up

The primary Organizer should log in and add any additional Organizers, enter doctor profiles, and add patients using the left panel menu to navigate through the application screens.



Show or Hide the left panel menu

Overview of key information for your Organization.

List all Orbs and Receivers registered to your Organization and their current status.

Maintain patient information, view image and video data files, and manage cases.

Maintain Doctor profiles for your Organization

Maintain Organizer profiles and add additional Organizers.

Receivers registered to your Organization and Orbs that have been paired with those Receivers and their current status will automatically show up in list on the Devices screen.

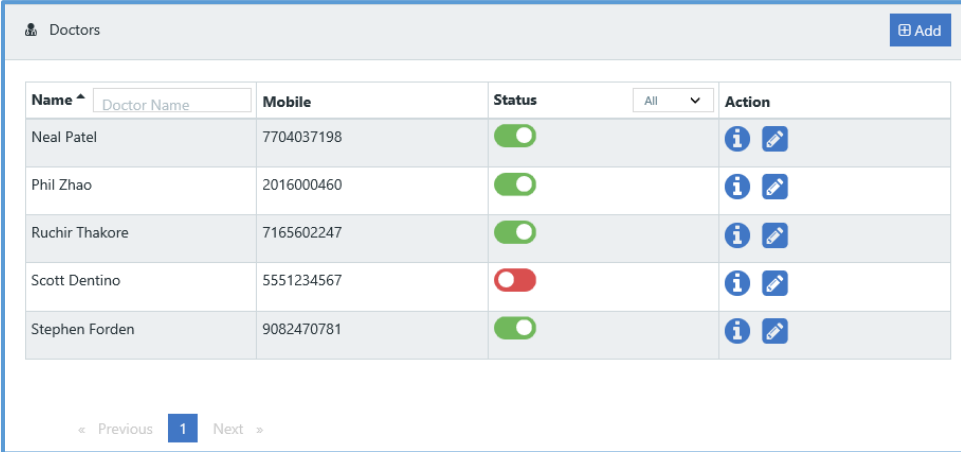
Device Name	Type	Status	Firmware Version	Action
SD_Rec1	Receiver	Offline	3.5.4.9	
SD_Orb1	Camera	Offline	3.5.4.9	
SD_Test	Receiver	Online	3.5.4.9	

eVS User Manual (Instructions for Use)

5.5.2.1. Enter a Doctor profile.

Doctors should be added so they can be linked to patient cases, access patient image and video files, and add cases.

- Use the add button to create a doctor profile.

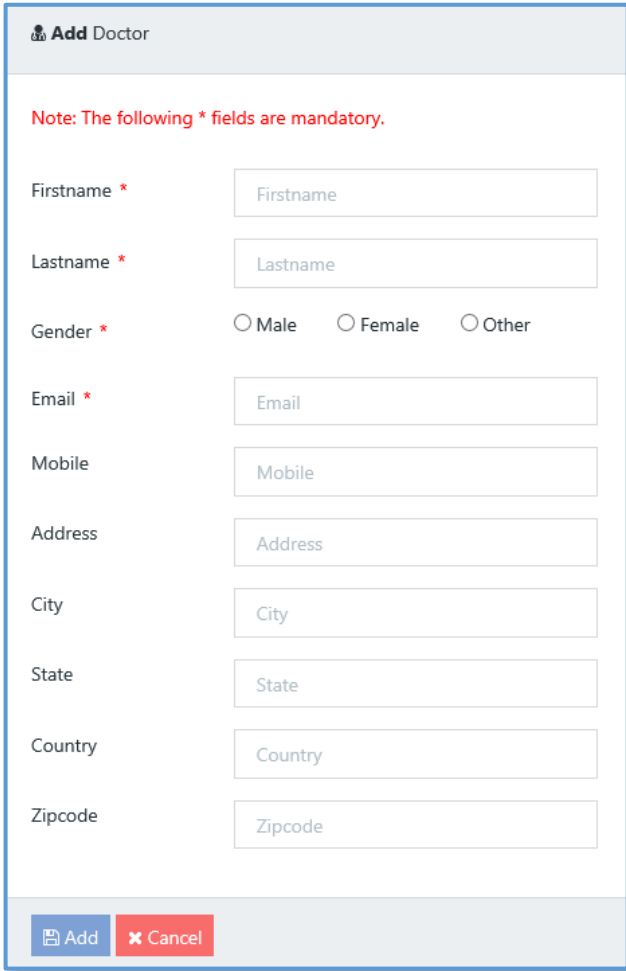


The screenshot shows a web interface for managing doctors. At the top, there is a header with a person icon, the text "Doctors", and a blue "Add" button. Below the header is a table with the following columns: "Name" (with a dropdown arrow and a placeholder "Doctor Name"), "Mobile", "Status" (with a dropdown menu set to "All"), and "Action". The table contains five rows of doctor profiles:

Name	Mobile	Status	Action
Neal Patel	7704037198	<input checked="" type="checkbox"/>	i ✎
Phil Zhao	2016000460	<input checked="" type="checkbox"/>	i ✎
Ruchir Thakore	7165602247	<input checked="" type="checkbox"/>	i ✎
Scott Dentino	5551234567	<input type="checkbox"/>	i ✎
Stephen Forden	9082470781	<input checked="" type="checkbox"/>	i ✎

At the bottom of the table, there are navigation controls: "« Previous", a blue box containing the number "1", and "Next »".

- Enter the mandatory information and click on the add icon.



The screenshot shows the "Add Doctor" form. At the top, there is a header with a person icon and the text "Add Doctor". Below the header, there is a red note: "Note: The following * fields are mandatory." The form contains the following fields:

- Firstname * (text input)
- Lastname * (text input)
- Gender * (radio buttons for Male, Female, Other)
- Email * (text input)
- Mobile (text input)
- Address (text input)
- City (text input)
- State (text input)
- Country (text input)
- Zipcode (text input)

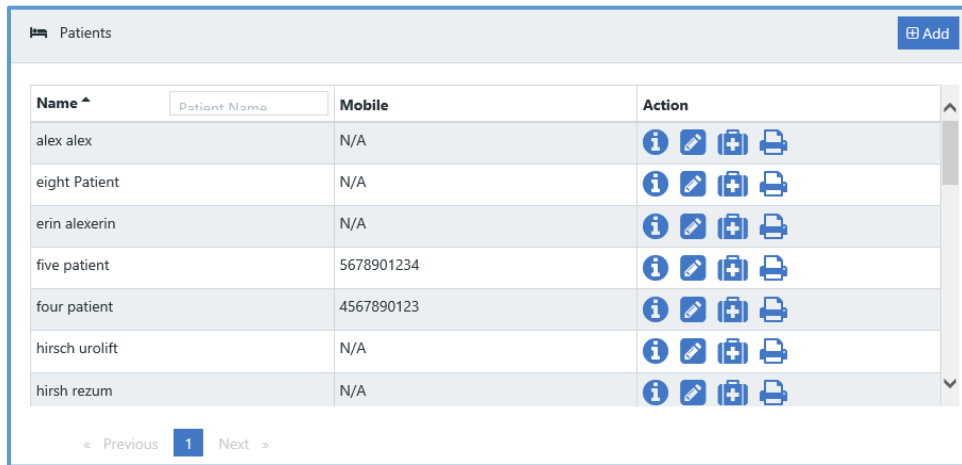
At the bottom of the form, there are two buttons: a blue "Add" button and a red "Cancel" button.

Once the doctor profile address has been added, the doctor can use their email address entered and the Forgot pass word link to obtain a temporary password for logging in to the application.

eVS User Manual (Instructions for Use)

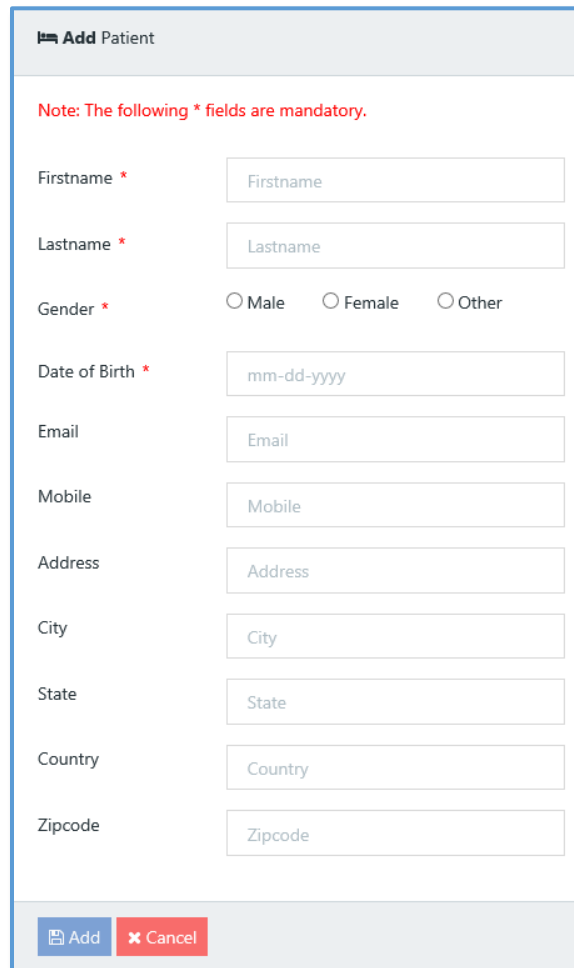
5.5.2.2. Enter a Patient profile.

- Use the add button to create a patient profile.



Name ^	Mobile	Action
alex alex	N/A	
eight Patient	N/A	
erin alexerin	N/A	
five patient	5678901234	
four patient	4567890123	
hirsch urolift	N/A	
hirsh rezum	N/A	

- Enter the mandatory information and click on the add icon.



Add Patient

Note: The following * fields are mandatory.

Firstname *

Lastname *

Gender * Male Female Other

Date of Birth *

Email

Mobile

Address

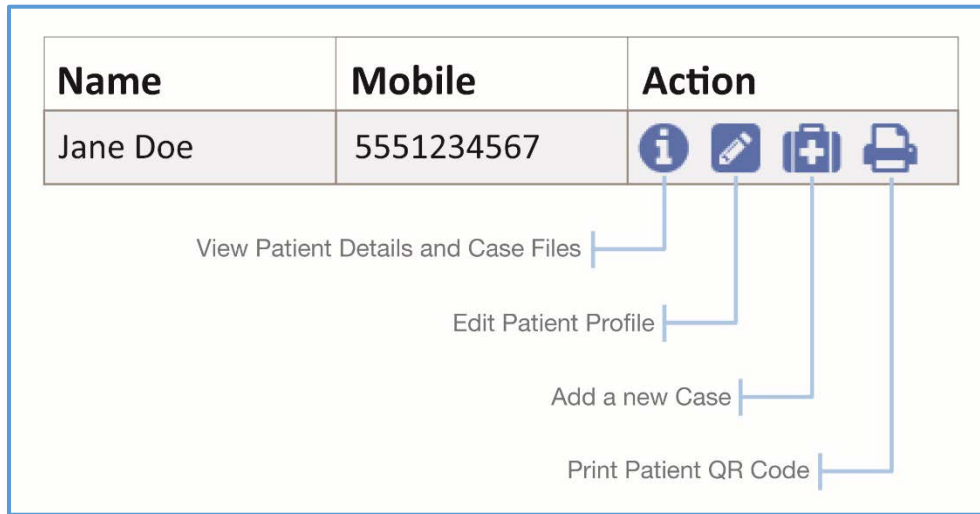
City

State

Country

Zipcode

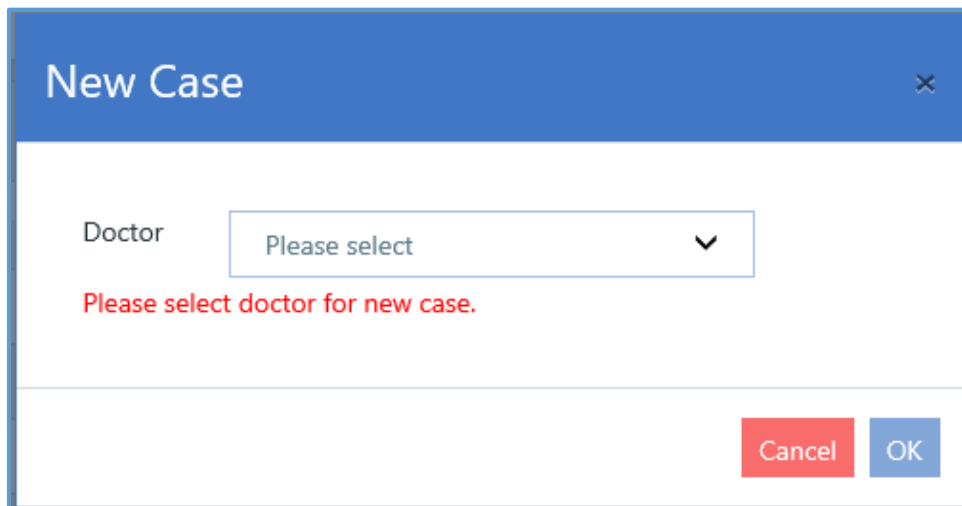
Patient Actions



5.5.3. Set up a Case

Entering a case prior to a scheduled procedure enables starting the eVS using the token method by selecting the case. This will associate the doctor and patient with the procedure, allowing for all collected files to be stored by patient, and procedure date and time.

- Click on the Add a New Case icon from the Patient Details screen for the entered patient record.
- Select the doctor that will be performing the procedure.



A case will be created for that patient with the current date.

5.6. Accessing and Managing Your Data Files

During normal system operation captured video and images are uploaded to the connected Receiver at the end of each procedure. If for some reason the Orb to Receiver connection is dropped, all the files stored on the Orb will upload (sync) the next time it connects to a Receiver and concludes a procedure.

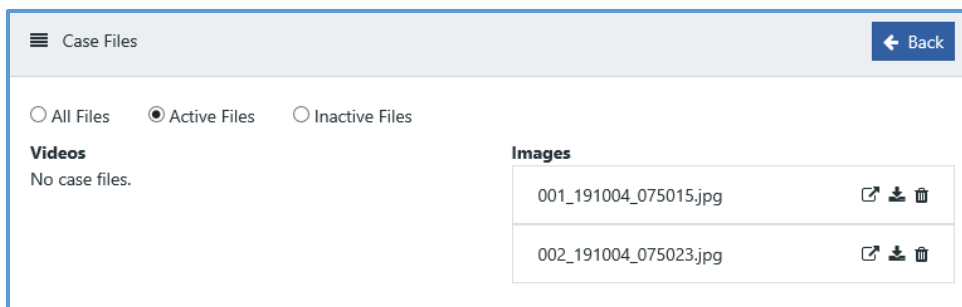
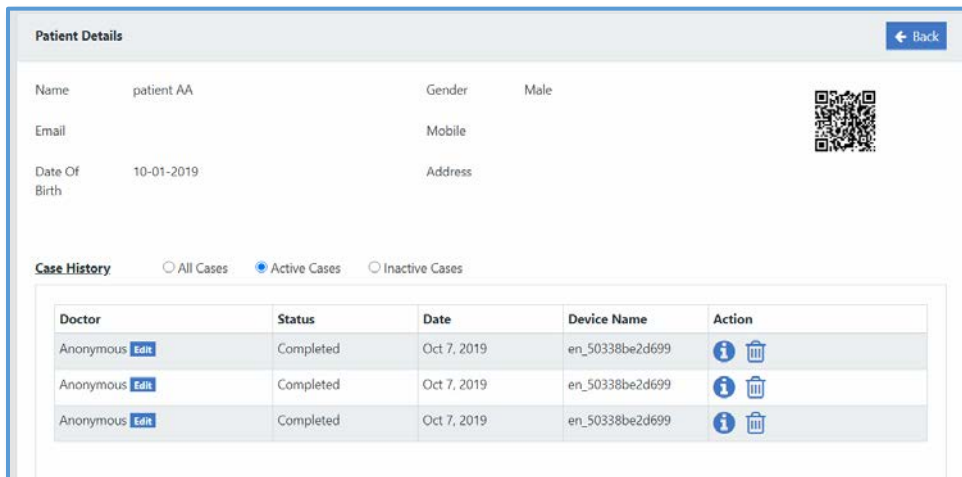
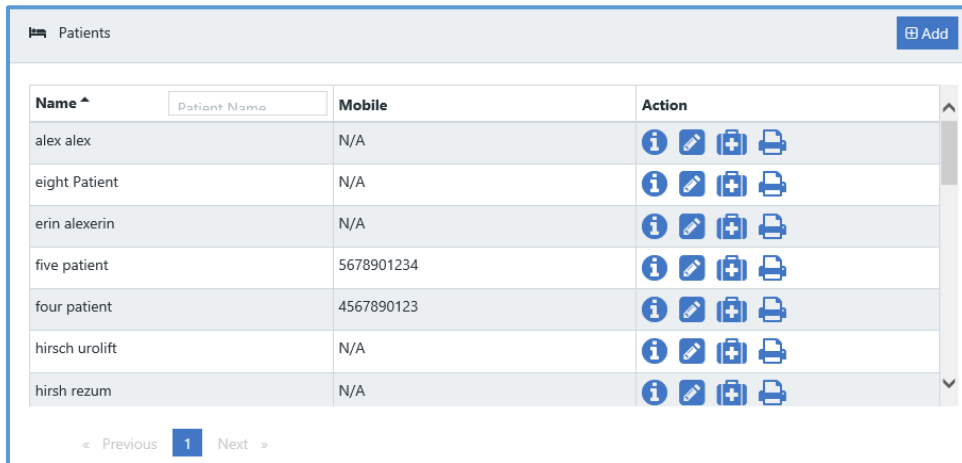
Once files have been uploaded to the registered Receiver, those files can be viewed and easily uploaded to the Collective.Endoluxe.com using the remote display Patient Data screens.

eVS User Manual (Instructions for Use)



TIP: It is recommended that files uploaded to the collective.endoluxe.com be deleted from the Receiver using either the Patient Data screens or the Settings > Data screen to delete all patient data.

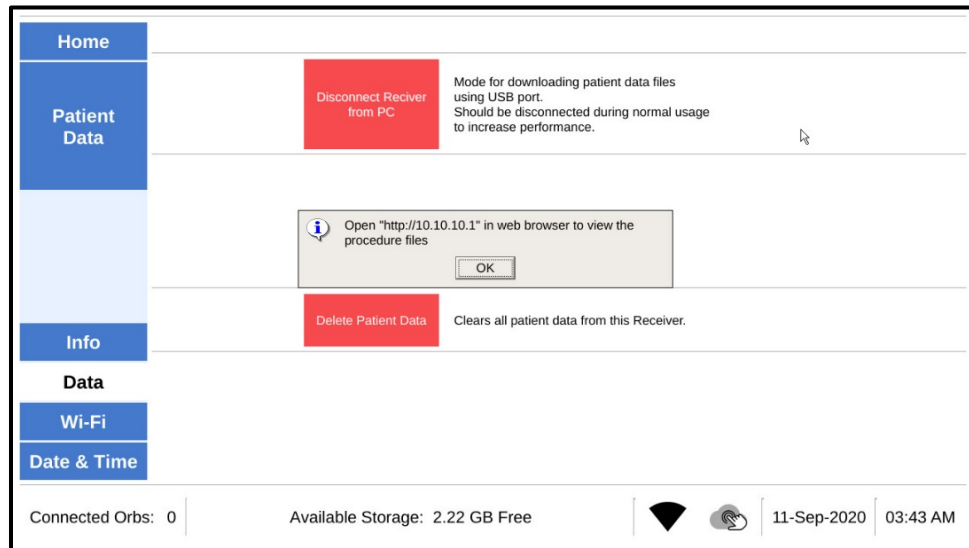
Patient data files can be easily accessed, viewed, downloaded, and deleted when logged into the collective.endoluxe.com once they have been uploaded. Just click on the Details icon from the Patients screen.



eVS User Manual (Instructions for Use)

Patient files can also be accessed directly from the Receiver using a USB-C to USB-A cable (not an included accessory or accessory option.) connected to a PC.

- Connect USB-C to USB-A cable to the Receiver using the USB-C port. Plug the USB-A cable connector into your PC.
- Enable Connect Receiver to PC by clicking the button on the Settings: Data screen.



- Enter the provided web IP address from the remote display into a web browser on the PC.

6. Warranty

Endoluxe warrants the eVS and provided accessories to the registered owner for three years from the original date of purchase against materials or workmanship defects, and accessory or component failures including batteries.

This warranty does not apply to any product, device or component that has been subject to misuse, abuse, neglect, improper handling or operation, or that has been altered or tampered with by any person other than authorized service personnel.

An extended warranty covering the same period as the basic product warranty may be purchased at the time of the original purchase that provides for one Orb repair or replacement in the case of damage due to mishandling or misuse.

The customer is responsible for returning product to the factory for repair or battery replacement at their own expense. Product will be repaired and returned to the customer, or if necessary replaced.

Repaired or replaced product includes a ninety day warranty against materials and workmanship defects when the original warranty period has passed. Repairs will be billed to the customer in the same manner as out-of-warranty repairs if it is determined the fault was caused by misuse, mishandling, or abnormal conditions of operation.

This warranty as set forth herein is exclusive and in lieu of all other warranties, remedies, obligations, and liabilities of Endoluxe Inc., expressed or implied, including the implied warranties of merchantability and fitness for use and of consequential damages. These products are sold only for the purpose described herein, and such warranty is provided only to the purchaser. Endoluxe shall not be liable for any breach of warranty in any amount exceeding the purchase price of the product.

No agent, employee, or representative of Endoluxe has the authority to bind the Company to any other warranty, affirmation, or representation. This warranty is valid only to the original purchaser of products obtained directly from Endoluxe or an authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

This warranty is void if any WARNINGS, CAUTIONS, or NOTES are disregarded.

Product is carefully packaged to prevent damage during transit and is shipped freight outbound (F.O.B.) from Bettendorf, IA. Endoluxe's responsibility for ensuring damage-free delivery ends upon remission of the equipment to the carrier. Examine the shipment promptly upon receipt. If the product packaging appears damaged at the time of delivery, immediately check product for damage or malfunction. If there is damage or malfunction, please return the product immediately.

7. Maintenance and Service

7.1. Maintenance.

Use a lint free cloth dampened with tap water or alcohol wipes to keep all surfaces clean. The Orb touch screen display and coupler optics should be cleaned using a lint free microfiber cloth or lens paper.

Store the Orb docked in the Charger when not in use.

Do not submerge any of the eVS devices, cables or accessories into any cleaning solutions.

7.2. Service

Contact Customer Service to arrange for servicing.

There are no user serviceable parts. eVS devices must be returned to an authorized service center for servicing or repair.

Recommended that the Orb be sent in for battery replacement if degradation of charging performance is observed. Battery replacement timing is dependent upon actual usage conditions.

Expected service life is five years from the date of manufacture.

7.3. Support

Please call or email Customer Support for both eVS and Collective.Endoluxe.com support.

Customer support: 609-382-0080

7.4. Product Shut Down and Disposal

Simply unplug both Charger and Receiver power adapters to shut down the eVS.

The eVS does not contain any hazardous materials. Only dispose of the eVS devices and accessories per local applicable laws and hospital practices. Recommended that the Orb be returned to the authorized service center to recycle the Li-ion battery.


8. Specifications


Conditions	Specification	Value
Operating	Temperature	10 – 30°C (50 – 86°F)
	Relative Humidity	30 - 75%
	Atmospheric Pressure	780- 990 hPa (11 -14 PSia)
Storage and Shipping	Temperature	-20 – 60°C (0 – 140°F)
	Relative Humidity	30 - 75%
	Atmospheric Pressure	700hPa – 1060 hPa (10 – 15 PSia)


Device/Component	Specification	Value
Orb	Touch Screen Resolution	400X400
	Battery	Li-ion rechargeable, 3.6V, 3.4 Ah
	CMOS Resolution	640 X 480 at 30 fps with 2X2 pixel binning
	Charging Interface	USB-C Female
	Power	5V DC, 3A
	Processor	Quad core
	Wi-Fi	2.4 or 5 GHz
	LED Light	9000 Lux maximum
	Latency	90 ms maximum
	Storage	4.5 Gb
Charger	Power	5V DC, 3A
	Charging Interface	USB-C Male
Receiver	Power	5V DC, 3A
	HDMI Resolution	720P HD (1280 X 720)
	Process	Dual core
	Wi-Fi	2.4 or 5 GHz
Power Adapter	Latency	170 ms maximum
	Power	100-240V~, 50-60Hz, 0.32A
	Power Output	5V DC, 3A
HDMI Cable	Grade	Medical Device
	Shielding	Double
	Length	6.0'
	Connectors	Gold plated
	Speed	18 GB/s (High)
Mouse	Protection	EMI/RFI
	Interface	USB-A
USB-C Cable (Option)	Features	2 button, wheel
	Interface	USB-C Male to USB-C Male
Light Adapter(s)	Length	6.0'
	Material	Ferritic Stainless Steel
Light Adapter (Option)	Length	13mm or 14 mm
	Material	Ferritic Stainless Steel
	Optics	Acrylic light pipe


9. Symbols


9.1. Labels and Device Markings


	Manufacturer
---	--------------


	Device item or model number
---	-----------------------------


	Manufacturer's processing batch or lot identification
---	---


	Temperature range
---	-------------------


	Relative humidity range
---	-------------------------


	Atmospheric Pressure range
---	----------------------------

	Wi-Fi capability indicator.
---	-----------------------------

	Federal Communications Commission (FCC) certification mark indicates the Wi-Fi chipsets meet the FCC requirements for electromagnetic interference.
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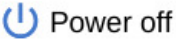

	Waste Electrical and Electronic Equipment Directive (WEEE Directive). Indicates electrical equipment placed on the market after 2005. See European Community Directive 2012/19/EU on waste electrical and electronic equipment for more information.
---	--

	MET Labs electrical safety certification mark
---	---

	Doctor should review the eVS User Manual for operational instructions and safety warnings.
---	--

10. Icons

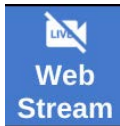
10.1. Device User Interfaces

	Safety warning
	Initiate a procedure mode using a token for a scheduled patient procedure.
	Initiate a procedure mode by scanning a patient QR code.
	Initiate a procedure in anonymous mode.
	Puck LED intensity indicator in procedure mode
	Battery charge level indicator in procedure mode
	Decrease setting value
	Increase setting value
	Decrease Puck LED intensity in procedure mode
	Increase Puck LED intensity in procedure mode
	Delete all stored patient image files
	Red, Green and Blue values for White Balance manual settings
	Shut down the Receiver
	Start and stop recording during a procedure from the remote display.

eVS User Manual (Instructions for Use)



Take photo during procedure from remote display.



Initiate and stop live streaming during a procedure from the remote display.



Battery charge indicator during procedure from the remote display



End procedure from the remote display



Exposure controls during procedure from the remote display



White Balance controls during procedure from the remote display



Puck LED intensity control during procedure from the remote display



Decrease setting value from the remote display



Increase setting value from the remote display.



Wi-Fi status – not connected to external router



Wi-Fi status – connected to external router



Collective.endoluxe.com status – not registered or connected




















Collective.endoluxe.com status – registered and connected



Rescan external Wi-Fi routers from remote display

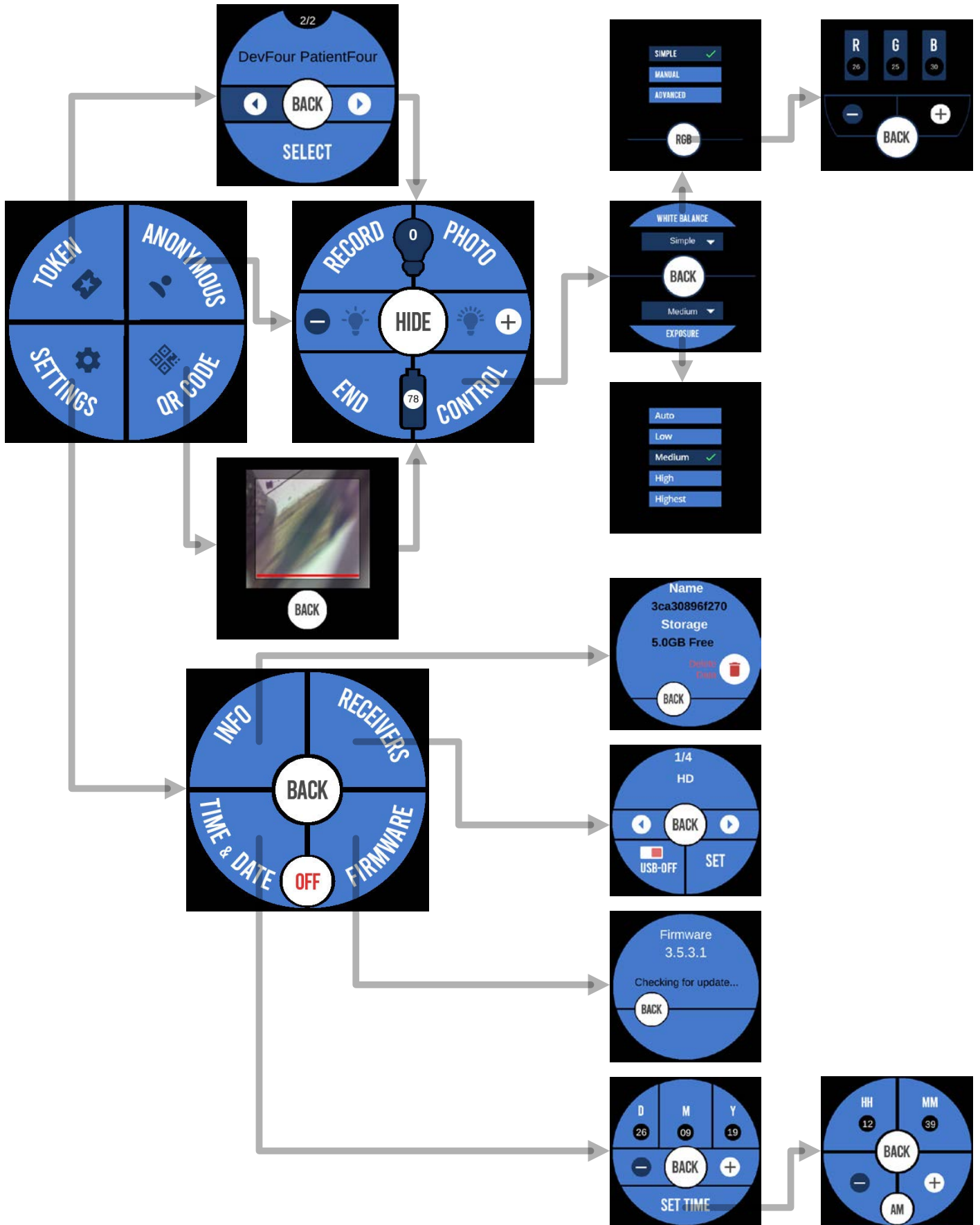
eVS User Manual (Instructions for Use)

10.2. Collective.Endoluxe.com

	Show or hide left menu panel
	Devices - Orbs or Receivers
	Doctors
	Patients
	Cases (procedures)
	Mouse over for information
	Link to record Information
	Link to edit record information
	Link to add a new case
	Link to print a patient QR code
	Play video file
	View image file
	Download video or image file
	Delete (inactivate file or record)
	Add a record
	Navigate back to the previous screen
	Request device log files be uploaded

11. UI Navigation Reference.

ORB UI NAVIGATION



eVS User Manual (Instructions for Use)

Remote Display UI NAVIGATION

